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Testimony

Mr. Chairman, and Members of the Committee:

I am pleased to be here today to discuss with you the important constitutional, international law and public policy issues raised by S. 334. The views expressed herein, of course, are strictly my own and not those of Emory University or its School of Law.

To summarize my views at the outset, I have four objections to S. 334 ("the Dorgan Bill). First, to the extent that it seeks to regulate the exclusively foreign operations of foreign drug manufacturers in foreign markets, the Dorgan Bill may be unconstitutional. Second, even if assumed to be constitutional, the Bill's extensive and heavy handed regulation of foreign drug manufacturers in foreign markets threatens to raise drug prices abroad and otherwise violate the fundamental principle of comity by undermining the policies of other countries. Not only will this violate principles of international law and create animosity toward the United States, it will also invite other countries to regulate conduct in the United States for the benefit of their economies, regardless of adverse effects on American interests. Third, the purpose of the Bill's intrusive provisions is to impose other countries' drug price controls on drugs consumed in the United States. But if drug price controls were a good idea, they could be imposed directly in this country without interfering with other countries' regulation of their own pharmaceutical markets. In that case, they would not be imposed by foreign governments under foreign legal standards unchecked by either Congressional oversight or judicial review. Instead, they could be imposed by an American regulator under American legal standards, subject to oversight by the Congress and review in the courts. Fourth, drug price controls are not a good idea, whether imposed directly by new legislation or indirectly by the Dorgan Bill. If the Bill operates as it sponsors hope, it will seriously undermine the incentives to innovation in the drug industry that the patent laws currently provide.

Constitutional Issues.

Congress's Constitutional authority to enact the Dorgan Bill must come from the Commerce Clause, particularly the "Power…To regulate Commerce with foreign Nations." U.S. Const. Art. I, § 8. cl. 3. This provision empowers Congress to regulate our international trade. Several provisions of S. 334 seek to coerce foreign manufacturers which produce drugs that are not for sale in the United States to supply those products for export to the U.S. against their will. See S. 334, § (n)(1) at 72-86. These provisions also impose a duty to supply exporters with other drugs that will not be exported to America, but rather consumed abroad, and regulate the prices for those coerced sales. See S. 334, §§ (n)(1)(A), (C), & (D). But when foreign manufacturers choose not to ship certain products to this country or agree with third parties to stay out of that trade, it is hard to see how Congress can legitimately regulate those decisions under the guise of regulating the foreign commerce of the United States.

One can argue that their decision not to export to the United States affects the foreign commerce of this country. As globalization proceeds, output and consumption decisions in other countries will increasingly have some economic effects on the prices and quantities of goods exported to the United States. For example, it has been reported in the press that the growing demand for petroleum products in China and other developing nations has diverted supplies from the United States, causing higher gasoline prices here and around the world. In a manner of speaking, then, the consumption decisions of Chinese industries and consumers are affecting petroleum exports to the United States, a part of our "foreign commerce."

But this argument proves too much. It would provide a rationale for Congress to regulate the entire world economy. This certainly was not intended by the Framers, nor can it be justified as a reasonable expansion of Congressional power to fit modern conditions. The provisions of the Constitution must be given a reasonable interpretation. A reading of the commerce clause extending the legislative jurisdiction of the United States to virtually the entire world economy cannot be reasonable.

International Law and Comity Issues.

Under current international law a nation may regulate conduct outside its territory that has significant effects within its territory. This is the principle that justifies, e.g., the extraterritorial application of our antitrust laws to foreign nationals for conduct in their own countries and, as most dramatically seen in the EU's prohibition of the GE/Honeywell merger, the extraterritorial application of other countries' laws to the activities of Americans taken in the United States.

To the extent that provisions of the Dorgan Bill would attempt to coerce foreign manufacturers, who are directly or indirectly engaged in commerce, to export to the United States and to sell in their own countries other drugs, which will not be exported to the U.S., at controlled prices to exporters, the legislation's extraterritorial effect would violate international law.

The "significant effects" test permits very intrusive extraterritorial regulation, as the GE/Honeywell decision illustrated. To moderate such effects, nations traditionally have voluntarily followed the principle of prescriptive comity, which counsels against regulation that unreasonably interferes with other countries' efforts to regulate their own affairs. Thus legislatures and courts have foregone opportunities to regulate within other countries to avoid undue interference with those countries' self-governance. For example, the Supreme Court "ordinarily construes ambiguous statutes to avoid unreasonable interference with the sovereign authority of other nations." F. Hoffman-LaRoche Ltd. v. Empagran S. A., 159 L.Ed. 2d 226, 236 (2004)(Breyer, J.); see also Hartford Fire Ins. Co. v. California, 509 U.S. 764, 812-19 (1993)(Scalia, J., dissenting)(discussing use of prescriptive comity to construe statutes). Indeed, the statute construed in Empagran, the Foreign Trade Antitrust Improvements Act of 1982, was passed in 1982 to ensure that the Sherman Act would not be unreasonably applied extraterritorially. Empagran, 159 L.Ed.

2d at 240.

Nations do not follow the comity principle just to be nice. They do so as a matter of enlightened self-interest, in the realization that extraterritorial regulation is a two-way street. A nation that extends the extraterritorial reach of its laws unreasonably can expect the same treatment in return. Legislatures and courts around the world have exercised self-restraint as a matter of mutual self-interest.

The provisions of S. 334, even if assumed to be constitutional and valid under international law, violate these principles of prescriptive comity. In essence, the bill intrusively regulates drug manufacturers in other countries, both as described above and in myriad other ways. These provisions are remarkably intrusive into other countries' affairs. At the least, they will stir up resentment toward the United States. It is hard to believe that the presence of FDA inspectors abroad will not be seen as a slur against other countries' drug regulations and yet another example of American exceptionalism and "imperialism." Other provisions add injury to this insult and may provoke more than mere resentment. The most glaring example is the requirement to sell for export to the United States at local prices. In many cases companies that sell both in this country and abroad, the primary targets of the Bill, will raise foreign prices or even forgo sales in other countries altogether rather than lose U.S. revenues.

In response to these injuries, other countries will be tempted to retaliate against the American interests by adopting similar requirements where their products are sold for less in this country than at home. For example, Japan could require its camera and electronics firms to sell in the United States at (higher) Japanese domestic prices.

Even if other countries do not retaliate in kind, the Dorgan Bill would set a bad precedent that erodes the principle of comity, to the detriment of American sovereignty and interests. In today's interdependent global economy many nations can justify extraterritorial regulation of American conduct under the effects test used in international law. If the United States aggressively and insensitively promotes its own interests via the extraterritorial application of its laws, it can hardly expect other countries to exercise self-restraint. This is already a serious problem in antitrust, as the confusion and conflict caused by the worldwide application of over 100 countries' competition laws has led to calls, in America as well as abroad, for a supranational competition law under the auspices of, e.g., the WTO.

Form of Drug Price Control Regime Issues.

The Bill is clearly aimed at drug companies that sell in both the United States and in other countries, most notably Canada, where foreign price controls force them to charge lower prices. By forcing these companies or their foreign affiliates and licensees to supply the American market from abroad, especially from Canada, the Bill seeks to import these foreign price controls into the United States.

But if drug price controls are a good idea, they should be directly imposed by our government in a straightforward manner, rather than in this backdoor, Rube Goldberg fashion. Under the Dorgan Bill the price controls of any of the foreign governments in the Bill's list of "permitted countries" may be imposed indirectly on American manufacturers. These controlled prices will be imposed by foreign governments which do not answer to American voters. They will be imposed under foreign legal standards by foreign regulatory bodies using foreign administrative procedure. If subject to judicial review at all, it would be available only in foreign courts. These agencies and their regulations will be beyond the checks and balances of Congressional oversight and judicial review in American courts.

By contrast, direct controls under a regulatory regime adopted by our Congress would be authorized by a statue enacted under the constitutional and political constraints of our system of government, by the United States Congress responding to the policy preferences of American voters. It would be implemented by an agency of the United States government, pursuant to U.S. statutory standards, under the procedural and judicial review procedures contained in the enabling legislation, the Administrative Procedure Act and the Constitution.

In short, an American price control system would be an action of the United States government, operating for the sole benefit of American consumers under American legal and constitutional principles, subject to American political and legal controls. These are the benefits of any regulatory regime created by our sovereign government. If drug price controls are a good idea, why would we delegate this task to foreign governments, rather than to our own?

Innovation Issues.

If the Dorgan Bill operates as its sponsors intend, it might well remove the incentives to innovation, provided by U.S. patent policy, that have made the American drug industry the leading provider of new medications. This is why there has been no serious move for drug price controls. Instead, public policy has gone in the exact opposite direction, giving the creators of new drugs patent rights that protect them from competitive pressures for a limited statutory period. This patent protection is justified as a reasonable inducement for innovation.

The economic theory of the Dorgan Bill appears to be that the profit incentives currently provided by drug patents are excessive, not necessary to induce the research and development of new drugs. This thesis is based on the fact that drug companies make enough in Canada and other price controlling countries to justify production and sales there.

This theory is wrong. Once a new drug has been developed, the expenses of developing it have already been incurred. They are what economists call sunk costs. A rational seller will sell, if need be, at a low price that does not allow it to recover these sunk costs, so long as the sales do permit it to cover the current costs of production. This is especially true if the seller can charge enough in other markets to recover its sunk costs.

We see this all the time in the travel industry, as hotels rent rooms and airlines sell seats at very low prices rather than see them go empty. As long as the hotel or airline recovers its immediate out of pocket costs, the low price makes sense. But as we are now seeing in the airline industry, a carrier cannot survive if too many of its seats go at these low prices.

A similar principle applies to the drug industry. It makes business sense to sell in Canada as long as the controlled prices cover the out of pocket costs of producing and the distributing the drugs there. But this does not mean that Canadian price levels would be sufficient to induce the research and development necessary to produce new medications.

This is not just a theoretical argument. If Canadian and European drug prices are sufficient to induce innovation, why do those countries depend on the American drug industry for new drugs? Why don't their domestic drug companies match ours? Canadians may argue their population and GDP are to small to support a domestic drug industry, but Europeans cannot. The European Union's population and GDP are as large as our own. Yet most new drugs continue to be developed in the United States.

In sum, the Dorgan Bill raises serious issues of constitutional and international law, would subject American interests to foreign regulatory regimes, and would threaten the incentives that make this country the leading developer of lifesaving new medications. It should not be adopted.